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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,376	09/25/2003	Janina Baranowska-Kortylewicz	0685-UNMC.63184	1854

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,376	Applicant(s) BARANOWSKA-KORTYLEWICZ ET AL.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 9/30/2005 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claim 18 has been amended.
2. Remarks drawn to Claim objections and rejections under 35 USC 102 and 103.

Claims 1-18 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

The objection to claim 18 for the misspelled term “imagining” has been overcome by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term lower alkyl. In the absence of a definition for the term lower in the claim, the claim is rendered indefinite.

Claims 5-9, which depend from claim 1, recite specific structural formulas for a conjugate. All of the formulae have a dexoxyuridine (hydrogen at the 5 position replaced by I-

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125 label) for the nucleobase moiety. Claim 1 is drawn to a conjugate that has a thymidine moiety (which has a methyl group at the 5 position of the base) for the base moiety. It is not clear what applicants intend.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 102

Claims 1-4 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Quivy et al (US 5,096,694) has been overcome by applicants arguments.

Claim Rejections - 35 USC § 103

Claims 1-4 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quivy et al (US 5,096,694) has been overcome by applicants arguments.

The following new rejection is made of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10059990 ('990 patent) newly cited in combination with Quivy et al (US 5,096,694) of record and Downer et al (Nuclear Medicine and Biology (2001, 28, 613-626) newly cited.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The '990 patent teaches radioactively labeled uridine derivatives of structural formula I containing phospho groups (page 1 of Japanese version and English abstract), with radioactive metal nucleus species. These radiolabelled uridine derivatives of this invention are useful in imaging tumors (English abstract- Advantage, page 2). However, the '990 patent does not specifically teach the use of radioisotopes or conjugates comprising dihydrotestosterone as instantly claimed.

Quivy et al teaches conjugates of thymidine labeled with Auger electron emitting radioisotopes like I-123 (col. 2, lines 16-64). These conjugates are used to treat a number of cancers with high concentrations of receptors for estrogens, progestagens and or androgens,

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which provide utility for the treatment of breast, uterus, ovary and prostate cancers (col. 4, lines 18-44). Quivy does not state specifically that a scintograph is used to image tumor. However, Quivy does cite that the radionuclide (I-123 or I-125) is useful in radioimaging wherein one of the principal instruments used for radioimaging is a scintigraph. Quivy does not teach a thymidine that has phospho groups or dihydrotestosterone attached to it.

Downer et al teach that dihydrotestosterone was found to have a high uptake by prostate at 1 hour (page 619; section 3.3, lines bridging left and right columns). Cancers, especially prostate cancers express high amounts of androgen receptors. Hence androgens, like testosterone are useful in diagnosis and imaging of cancers and tumors (page 613, Introduction). However, Downer et al do not teach the use of specific Auger electron emitting isotopes or conjugates comprising phospho-thymidine and dihydrotestosterone as instantly claimed.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make a radio labeled conjugate of thymidine and other bases containing phospho groups and dihydrotestosterone and use the same in a method treatment and imaging of tumors and cancers as instantly claimed with a reasonable expectation of success since the use of such is taught in the prior art.

One of ordinary skill in the art would be motivated to make and use radiolabelled conjugates as instantly claimed because:

1. The '990 patent teaches the use of radiolabelled phospho uridine in tumor treatment and imaging.
2. Quivy teaches that radiolabels like I-123 or I-125 will enable specifically the destruction of cancer cells and also help in imaging (col. 4, lines 34-39).

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3. Both Quivy and Downer teach that androgens and especially dihydrotestosterone have high uptake due to the high concentrations of androgen receptors in cancers (Quivy, col. 4, lines 26-33).

One of ordinary skill in the art will be motivated to make a phospho containing thymidine or uridine with an Auger electron emitting radiolabel and dihydrotestosterone and use the same in a method for treating and imaging tumors and cancers since such a combination has the advantage of high uptake due to the presence of the dihydrotestosterone moiety and the cancer cell destroying and imaging ability because of the presence of the Auger electron emitting radioisotope in a single compound.

Quivey does not specifically cite the route of administration or the timetable for administration of the conjugates of his invention. However, given routine experimentation common to the practice of an invention, one of ordinary skill in the art would have been provided with a motivation and a reasonable expectation of success in the use of art accepted routes of administration like intravenous, intraperitoneal and intratumor over a daily or yearly period for the treatment as instantly claimed. One of ordinary skill in the art routinely adjusts the dosage and timetable of administration based on the type of cancer or tumor as well as the patient's tolerance and metabolism.

Conclusion

Claims 1-18 are rejected

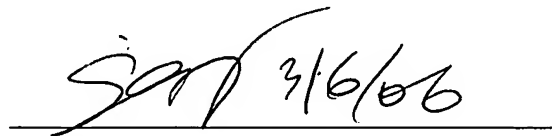
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

A handwritten signature in black ink, appearing to read 'S. Jiang', followed by the date '3/6/06'. The signature is written over a horizontal line.

Shaojia A. Jiang
Supervisory Patent Examiner
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